Remarks

Claims 141-146, 148, 150-168, 170-175, 179, and181-208 are pending in the present application.

Claims 205-208 have been newly added. New claim 205 is directed to the "method of claim 141, wherein the agent comprises a high-density lipoprotein." New claim 206 is directed to the "method of claim 141, wherein the agent is a reconstituted high-density lipoprotein." New claim 207 is directed to the "method of claim 141, wherein the agent is a combination of non-cholesterol lipid components capable of reconstituting a high-density lipoprotein comprising one or more of a sphingolipid and a phospholipid, and one or more of a glyceride and a triglyceride." New claim 208 is directed to the "method of claim 141, wherein the agent is reconstituted high-density lipoprotein and a combination of non-cholesterol lipid components capable of reconstituting a high-density lipoprotein comprising one or more of a sphingolipid and a phospholipid, and one or more of a glyceride and a triglyceride."

Support for new claims 205-208 appears throughout the specification and claims as originally filed. No new matter has been added.

Claims 1-140, 147, 149, 169, 176-178, and 180, have previously been cancelled without prejudice or disclaimer. Claim 183 has been amended to correct a minor error. No new matter has been added.

Claims 141-146, 148, 150-168, 10-175, 179, and 181-204 have been rejected.

However, Applicant notes that claims 159-167, 172-173, 176-179, and 181-183, were previously objected to as being dependent upon a rejected base claim, and were indicated allowable if rewritten in independent form including all of the limitations of any intervening claim. Accordingly, claims 184-197 were previously added and correspond to objected to claims 159-167, 172-173, and 181-183, written in independent form and including all of the limitations of any intervening claims.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 141-146, 148, 150-168, 170-175, 179 and 181-204 have been rejected under 35 USC § 112, first paragraph as failing to comply with the written description requirement.

The Examiner asserts that the "claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a reconstituted high-density lipoprotein. The instant specification describes a few compounds as high-density lipoprotein. In the absence of understanding the compounds covered by the phrase 'a reconstituted high-density lipoprotein,' the artisan does not accept that applicant was in possession of the claimed invention."

In view of the following, this rejection is respectfully traversed.

The test under 35 USC § 112, first paragraph, for determining compliance with the written description requirement is whether the application clearly conveys that an applicant has invented the subject matter which is claimed. *In re Barker*, 194 USPQ 470, 473 (CCPA 1977); **MPEP § 2163**. Also, the applicant must convey to the public what the applicant claims as the invention so that the public may ascertain if the patent applicant claims anything in common use or already known. **MPEP § 2163**. Lastly, the specification must convey that the applicant was in possession of the invention. **MPEP § 2163**. The Examiner is respectfully reminded that the Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 191USPQ 90, 98 (CCPA 1976).

In addition, Applicant notes that the United States Patent and Trademark Offices' "Revised Interim Written Description Guidelines Training Materials" states the following at page 4:

> It is assumed at this point in the analysis that the specification has been reviewed and an appropriate search of the claimed subject matter has been conducted. It is also assumed that the examiner has identified which features of the claimed invention are conventional taking into account the body of existing prior art. There is a ***strong presumption that an adequate written description of the claimed invention is present in the specification as filed***. If the examiner determines that the application does not comply with the written description requirement, the ***examiner has the initial burden***, after a thorough reading and evaluation of the content of the application, of ***presenting evidence or reasons*** why a person skilled in the art would not recognize that the written description of the invention

> provides support for the claims. It should also be noted that the test for an adequate written description is separate and distinct from the test under the enablement criteria of 35 U.S.C. § 112 first paragraph. ***The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. § 112 para. 1, for lack of adequate written description.*** (emphasis added)

See also page 6 of the Guidelines "Written Description Amended or New Claims...Decision Tree."

In the present case, the Examiner has provided ***no reasons or evidence*** as to why a person skilled in the art would not recognize that the written description of the invention provides support for the present claims. Rather, the Examiner simply states "In the absence of understanding the compounds...the artisan does not accept that applicant was in possession of the claimed invention." Accordingly, the Examiner has not transferred the burden for establishing adequate written description.

In addition, assuming *arguendo* that the initial burden has been met by the Examiner, the present specification clearly describes a "reconstituted high-density lipoprotein" at page 6, last paragraph, as follows:

> The term *"and at least one other lipid component of HDL other than cholesterol and cholesteryl-ester"* refers to glycerides, glycerol and triglycerides. In accordance with the invention glycerides and triglycerides which are not present naturally in HDL, but have an analogous function to glycerides and triglycerides present in HDL may also be used. The composition of matter comprising the non-cholesterol and the non-cholesteryl-ester lipid components of HDL (generally phospholipids, triglycerides and glycerides) is termed *"reconstituted HDL"* (Gillote *et al., J. Biol. Chem.*, **271**:23792-23798, 1996). This term refers to a complex comprising phospholipids, triglycerides and glycerides, which differs from natural HDL by the absence of cholesterol, cholesteryl-esters, and apolipoproteins.

Further, Applicant submits that the skilled artisan would recognize that the term reconstituted HDL (rHDL) connotes a well defined composition of constituents. In fact, numerous prior US Patents/applications have been granted/filed with the composition being an essential part of the invention and the term being part of the claim. For example:

- US Patent 7,053,049 to *Luescher et al.*, discloses (in claim 1) a method for treating a certain disorder by administering an amount of *reconstituted HDL*.

- US Patent application 2004/0266660 discloses (in claim 11) a composition comprising rHDL for the treatment of ischemia.

In addition, the term "reconstituted HDL" has been described regularly in literature. For example, a Medline search for the term "Reconstituted HDL" for the time period 1950-1996 – yields 127 publications. Again, the specification provides on page 6, line 18 thereof that reconstituted HDL is a complex comprising phospholipids, triglycerides and glycerides, which differ from natural HDL by the absence of cholesterol, cholesteryl-esters, and apolipoproteins.

It is customary in the field that rHDL can be prepared in a range of molar ratios of protein/phospholipids and that it is not necessarily the ratio which affects the efficacy of the rHDL but rather the presence or absence of specific constituents. Attached hereto, please find the following reference which describe rHDL: (i) Gillotte et al. 1996 (cited on page 6 of the present specification); (ii) Sakai et al. 1996; (iii) Bijsterbosch et al. 1996; (iv) Bolin and Jonas 1996; (v) Rye et al. 1995; (vi) Parker et al. 1995; and (vii) Bijsterbosch et al. 1994. The present

specification as well as the foregoing references, evidence that the term "reconstituted high-density lipoprotein" is well-established and readily understood by one of ordinary skill in the art to which the present invention pertains.

In view of the above, it is submitted that the claims are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, within the meaning of 35 USC § 112, first paragraph. Thus, the Examiner is respectfully requested to withdraw this rejection.

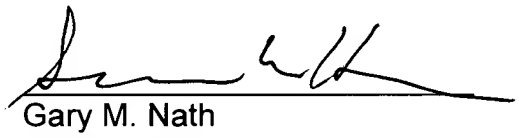
Conclusion

In view of the remarks set forth herein, Applicant submits that the pending claims are in condition for immediate allowance. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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